means prevents axial movement of the cartridge assembly relative to the dosage assembly.

45. The medication delivery device of claim 44, wherein the dosage assembly comprises a plunger means and a drive means and wherein the second coupling means is selected to ensure that uncoupling of the needle assembly from the dosage assembly does not result in movement of the plunger means relative to a removable cartridge that is housed in the cartridge assembly.

46. The medication delivery device of claim 45, wherein the first coupling means comprises a snap-lock means for allowing axial coupling and uncoupling of the needle assembly to and from the cartridge assembly without the need to rotate the needle assembly relative to the dosage assembly.

47. The medication delivery decide of claim 46, wherein the second coupling means comprises a threaded coupling and wherein the first coupling means is at least partially integrated into the needle assembly.

48. The medication delivery device of claim 47, wherein the snap lock means is fully integrated into the needle assembly.

REMARKS

Claims 1-13 and 19-33 have been canceled without prejudice or disclaimer. Claims 34-48 have been added and therefore are pending in the present application. Claims 34-48 are supported by the drawings, the original claims, and the specification.

It is respectfully submitted that the present amendment presents no new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

In the previous office action, the Examiner rejected claims 1, 19, 21-23 and 25-27 under 35 USC § 102(b) in view of Chanoch US Pat. No. 5,688,251 and rejected claims 28-33 under 35 USC § 103(a) in view of Chanoch. The Examiner dismissed the Applicants' previous arguments that their invention is novel and non-obvious because Chanoch does not disclose selection of a means for securing the needle to cartridge assembly and a means for securing the dosing assembly to the cartridge assembly such that the dosing assembly does not move relative to the cartridge assembly during removal or attachment of a needle. The Examiner has, ostensibly, taken the position that one of ordinary skill in the art would grasp the Chanoch cartridge assembly or both the Chancoch cartridge assembly and the Chanoch dosing assembly when removing or attaching a needle and therefore the dosing assembly would not move relative to the cartridge assembly during a needle change. The Examiner, also asserts that because Chanoch states that other means for mounting the needle cannula to the cartridge holder may be provided, it discloses that two different types of coupling means on a single device or that something other than threads as shown in the figures may be used.

Applicants note that even if the Examiner's view of Chanoch is correct, Chanoch does not disclose or even suggest a means for ensuring that the dosing assembly does not move relative to the cartridge assembly when the dosing assembly and the needle are intentionally grasped during a needle change. Chanoch is silent as to how and what criteria should be used when selecting a means for securing the needle assembly to the cartridge assembly and the cartridge assembly to the dosing assembly. Moreover, Chanoch fails to disclose or even suggest that the two securing means should be chosen so that when force is applied to remove (or attach) the needle while the

dosage assembly is grasped, the security of the dosage assembly to the cartridge assembly is not jeopardized.

As presently claimed in the new pending claims (i.e., claims 34-48), Applicants' invention specifically requires that the means for securing the needle to the cartridge assembly and the means for securing the cartridge assembly to the dosing assembly be chosen so that when the needle assembly and the dosing assembly are grasped and a force applied to both to remove (or attach) the needle assembly, the cartridge assembly remains securely fixed to the dosing assembly. Thus, it is irrelevant to the patentability of the present claims whether one would grasp the cartridge assembly during a needle change. By their own terms, the claims now require that when the dosing assembly and needle assembly are grasped during needle attachment or removal, the means for securing the dosing assembly to the cartridge assembly must prevent unintended axial movement of the dosage assembly relative to the cartridge assembly. By preventing the cartridge assembly from moving relative to the dosing assembly when changing a needle the accuracy of a subsequently administered dose can be guaranteed.

Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to

contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: August 15, 2002

Marc A. Began Reg. No. 48,829
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

Attorney Docket No.: 5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Application No.: 09/349,748 Group Art Unit: 3763

Filed: Feb. 11, 2002 Examiner: K. Sirmons

For: Medical Device

AMENDMENT UNDER 37 C.F.R. 1.111

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the telephonic conversations between Examiner Sirmons and Marc A. Began (attorney for the Applicants) on Jan 16, 2003 and on Jan 21, 2003, please amend the above-captioned application as follows (a marked up version pursuant to 37 C.F.R. 1.21 is attached hereto, where applicable):

IN THE CLAIMS:

34. (Amended) A medication delivery device comprising:

a cartridge assembly comprising a cartridge having a pierceable seal at one end and a moveable stopper at an opposite end;

a dosage assembly comprising a plunger means for acting on the stopper; a mechanism for setting a specified dose; and a drive means for advancing the plunger means to deliver the specified dose;

a needle assembly;

a first coupling means for coupling and uncoupling the needle assembly to and from the cartridge assembly;

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first coupling means comprises a snap lock; and

wherein the second coupling means is selected such that when a user grasps the needle assembly and applies a force to couple it to and to uncouple it from the cartridge assembly, while simultaneously grasping the dosage assembly and applying an equal but opposite force thereto, the cartridge assembly cannot not move axially with respect to the dosage assembly.

35. The medication delivery device of claim 34, wherein the first coupling means comprises a means for coupling or uncoupling the needle assembly through an axial movement of the needle assembly relative to the cartridge assembly and the second means comprises a threaded means.

36. The medication delivery device of claim 35, wherein the cartridge assembly comprises a housing for receiving the cartridge and wherein the snap lock is an integral part of the needle assembly..

37. A medication delivery device upon which a needle assembly can be mounted, the device comprising:

a cartridge assembly comprising a cartridge having a movable stopper at one end and a pierceable seal at an opposite end;

a dosage assembly comprising a mechanism for setting a specified dose, a plunger means for abutting the moveable stopper, and a drive means for driving the plunger means to deliver the set doseage;

a first coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly; and

a second coupling means for coupling and uncoupling a needle assembly to and from the cartridge assembly;

wherein the first and second coupling means are selected so that when a user grasps the needle assembly and applies force to the needle assembly to couple and uncouple it from the device while simultaneously grasping the dosage assembly and applying a equal and opposite force to the dosage assembly, the dosage assembly cannot move relative to the cartridge assembly, thereby ensuring that the plunger means remains abutted against the stopper; and

wherein the first or second coupling means comprises a snap lock.

38. The medication delivery device recited in claim 37, wherein the second coupling means comprises a threaded coupling means and wherein the second coupling means comprises a means for coupling and uncoupling through an axial movement of the needle assembly relative to the cartridge assembly.

39. The medication delivery device of claim 37, wherein the first coupling means comprises a means for uncoupling through an axial movement of the cartridge assembly relative to the dosing assembly.

40. The medication delivery device of claim 37, wherein the first coupling means comprises a threaded coupling means.

41. The medication delivery device of claim 37, wherein the cartridge assembly comprises a housing to accommodate the cartridge and wherein the second coupling means comprises a means for axially coupling or uncoupling the needle assembly from the cartridge assembly.

42. The medication delivery device of claim 37, wherein the second coupling means comprises a threaded coupling means.

43. A medication delivery device comprising:

a cartridge assembly comprising:

a housing capable of housing a removable cartridge that has a pierceable seal at one end, is filled with medication, and has a moveable stopper at an opposite end that when moved toward the medication pressurizes the medication; and

a needle mounting means for mounting a needle on the cartridge assembly;

a dosage assembly for delivering a set dose of medication, comprising:

a plunger means for moving the stopper, a dose setting means for setting a dose, and a drive means for driving the plunger means to deliver the set dose, wherein after a portion of medication is expelled from the cartridge, the plunger means abuts the stopper;

a first means for coupling and uncoupling a needle assembly to and from the cartridge assembly;

a second means for coupling and uncoupling the dosage assembly to and from the cartridge assembly;

wherein the first and second coupling means are chosen so that when a user simultaneously grasps the dosage assembly and the needle assembly and applies a force to the needle assembly to couple (or uncouple) the needle to or from the device the cartridge assembly is positively precluded from moving axially relative to the cartridge assembly; and

wherein at least the first or the second coupling means comprises a snap lock.

44. A medication delivery device comprising:

a cartridge assembly for housing a removable cartridge containing a medication;

a needle assembly;

a dosage assembly comprising a mechanism for setting a dosage less than the full amount of medication contained in the cartridge;

a first coupling means for coupling and uncoupling the needle to and from a removable cartridge housed in the cartridge assembly; and

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first coupling means comprises a snap lock; and

wherein the second coupling means is chosen so that when a user couples or uncouples the needle assembly from the cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, the second coupling means prevents axial movement of the cartridge assembly relative to the dosage assembly.

REMARKS

As per the Examiner's suggestion, the claims have been amended so that one of the coupling means comprises a snap lock. It is respectfully submitted that the present amendment presents no new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to

contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: January 21, 2003

Marc A. Began Reg. No. 48,829
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(212) 867-0123

VERSION WITH MARKINGS TO SHOW CHANGES MADE

34. (Amended) A medication delivery device comprising:

a cartridge assembly comprising a cartridge having a pierceable seal at one end and a moveable stopper at an opposite end;

a dosage assembly comprising a plunger means for acting on the stopper; a mechanism for setting a specified dose; and a drive means for advancing the plunger means to deliver the specified dose;

a needle assembly;

a first coupling means for coupling and uncoupling the needle assembly to and from the cartridge assembly;

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first coupling means comprises a snap lock; and

wherein the ~~first and~~ second coupling means are~~is~~ selected such that when a user grasps the needle assembly and applies a force to couple it to and to uncouple it from the cartridge assembly, while simultaneously grasping the dosage assembly and applying an equal but opposite force thereto, the cartridge assembly cannot not move axially with respect to the dosage assembly.

35. The medication delivery device of claim 34, wherein the first coupling means comprises a means for coupling or uncoupling the needle assembly through an axial movement of the needle assembly relative to the cartridge assembly and the second means comprises a threaded means.

36. The medication delivery device of claim 35, wherein the cartridge assembly comprises a housing for receiving the cartridge and wherein ~~the first coupling means comprises a snap lock and wherein~~ the snap lock is an integral part of the needle assembly.

37. A medication delivery device upon which a needle assembly can be mounted, the device comprising:

a cartridge assembly comprising a cartridge having a movable stopper at one end and a pierceable seal at an opposite end;

a dosage assembly comprising a mechanism for setting a specified dose, a plunger means for abutting the moveable stopper, and a drive means for driving the plunger means to deliver the set doseage;

a first coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly; and

a second coupling means for coupling and uncoupling a needle assembly to and from the cartridge assembly;

wherein the first and second coupling means are selected so that when a user grasps the needle assembly and applies force to the needle assembly to couple and uncouple it from the device while simultaneously grasping the dosage assembly and applying a equal and opposite force to the dosage assembly, the dosage assembly cannot move relative to the cartridge assembly, thereby ensuring that the plunger means remains abutted against the stopper and

wherein the first or second coupling means comprises a snap lock.

38. The medication delivery device recited in claim 37, wherein the second coupling means comprises a threaded coupling means and wherein the second coupling means comprises a means for coupling and uncoupling through an axial movement of the needle assembly relative to the cartridge assembly.

39. The medication delivery device of claim 37, wherein the first coupling means comprises a means for uncoupling through an axial movement of the cartridge assembly relative to the dosing assembly.

40. The medication delivery device of claim 37, wherein the first coupling means comprises a threaded coupling means.

41. The medication delivery device of claim 37, wherein the cartridge assembly comprises a housing to accommodate the cartridge and wherein the second coupling means comprises a means for axially coupling or uncoupling the needle assembly from the cartridge assembly.

42. The medication delivery device of claim 37, wherein the second coupling means comprises a threaded coupling means.

43. A medication delivery device comprising:

a cartridge assembly comprising:

a housing capable of housing a removable cartridge that has a pierceable seal at one end, is filled with medication, and has a moveable stopper at an opposite end that when moved toward the medication pressurizes the medication; and

a needle mounting means for mounting a needle on the cartridge assembly;

a dosage assembly for delivering a set dose of medication, comprising:

a plunger means for moving the stopper, a dose setting means for setting a dose, and a drive means for driving the plunger means to deliver the set dose, wherein after a portion of medication is expelled from the cartridge, the plunger means abuts the stopper;

a first means for coupling and uncoupling a needle assembly to and from the cartridge assembly; and

a second means for coupling and uncoupling the dosage assembly to and from the cartridge assembly,

wherein the first and second coupling means are chosen so that when a user simultaneously grasps the dosage assembly and the needle assembly and applies a force to the needle assembly to couple (or uncouple) the needle to or from the device the

cartridge assembly is positively precluded from moving axially relative to the cartridge assembly;

wherein at least the first or second coupling means comprises a snap lock.

44. A medication delivery device comprising:

a cartridge assembly for housing a removable cartridge containing a medication;

a needle assembly;

a dosage assembly comprising a mechanism for setting a dosage less than the full amount of medication contained in the cartridge;

a first coupling means for coupling and uncoupling the needle to and from a removable cartridge housed in the cartridge assembly; and

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first coupling means comprises a snap lock; and

wherein the ~~first and~~ second coupling means are ischosen so that when a user couples or uncouples the needle assembly from the cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, the second coupling means prevents axial movement of the cartridge assembly relative to the dosage assembly.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,748	07/08/1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085

26137 7590 05/15/2002

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036

EXAMINER	
SIRMONS, KEVIN C	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 05/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Notice of Allowability	Application No. 09/349,748	Applicant(s) BUCH-RASMUSSEN ET AL.	
	Examiner Kevin C. Simmons	Art Unit 3763	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address–

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/22/02.
2. ☒ The allowed claim(s) is/are 1-11.
3. ☒ The drawings filed on 1/16/02 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☒ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____.
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

1. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

2. ☐ CORRECTED DRAWINGS must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No. ____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

3. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Informal Patent Application (PTO-152)
3. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
4. ☐ Interview Summary (PTO-413), Paper No. ____.
5. ☐ Information Disclosure Statements (PTO-1449), Paper No. ____.
6. ☐ Examiner's Amendment/Comment
7. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other

DETAILED ACTION

Allowable Subject Matter

Claims 34-44 are allowable over the prior art of record at the time the invention was made.

The following is an examiner's statement of reasons for allowance: Claims 34, 37, 43 and 44 are allowable over the prior art of record because the prior art does not disclose or render obvious the combination of a first or second coupling means which comprises a snap lock for assisting in coupling or uncoupling of a needle assembly from a cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, thus preventing the cartridge assembly from moving axially with respect to the dosage assembly.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

KCS

Kevin C. Sirmons
Patent Examiner
1/23/03

BLC

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

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NOTICE OF ALLOWANCE AND FEE(S) DUE

26137 7590 01/27/2003

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036

EXAMINER	
SIRMONS, KEVIN C	
ART UNIT	**CLASS-SUBCLASS**
3763	604-232000

DATE MAILED: 01/27/2003

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,748	07/08/1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085

TITLE OF INVENTION: MEDICAL DEVICE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1300	$0	$1300	04/28/2003

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE
Commissioner for Patents
Washington, D.C. 20231
Fax (703)746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

26137 7590 04/27/2003

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FOUR TIMES SQUARE
NEW YORK, NY 10036

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,748	07/08/1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085

TITLE OF INVENTION: MEDICAL DEVICE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1300	$0	$1300	04/28/2003

EXAMINER	ART UNIT	CLASS-SUBCLASS
SIRMONS, KEVIN C	3763	604-232000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

☐ Issue Fee
☐ Publication Fee
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):

☐ A check in the amount of the fee(s) is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) (Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,748	07/08/1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085

26137 7590 01/27/2003

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036
UNITED STATES

EXAMINER	
SIRMONS, KEVIN C	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 01/27/2003

Determination of Patent Term Extension under 35 U.S.C. 154 (b)
(application filed after June 7, 1995 but prior to May 29, 2000)

The patent term extension is 0 days. Any patent to issue from the above identified application will include an indication of the 0 day extension on the front page.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,748	07/08/1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085

26137 7590 01/27/2003

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036
UNITED STATES

EXAMINER	
SIRMONS, KEVIN C	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 01/27/2003

Notice of Fee Increase on January 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. See Revision of Patent and Trademark Fees for Fiscal Year 2003; Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: http://www.uspto.gov/main/howtofees.htm.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

#21

05/20/03

OIPE JC64 MAY 0 5 2003 PATENT & TRADEMARK OFFICE

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE
Commissioner for Patents
Washington, D.C. 20231
Fax (703)746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use blank if appropriate)

26137 7590 01/22/2003

~~PATENT DEPARTMENT~~ MARC A. BEGAN, ESQ.
~~SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP~~
~~FOUR TIMES SQUARE~~
~~NEW YORK, NY 10036~~
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below.

Raghida Haji (Depositor's name)
R. Haji (Signature)
4-28-03 (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,748	07/08/1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085

TITLE OF INVENTION: MEDICAL DEVICE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1300	$0	$1300	04/28/2003

EXAMINER	ART UNIT	CLASS-SUBCLASS
SIMMONS, KEVIN C	3763	604-232000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 Marc A. Began, Esq.
2 Richard W. Bork, Esq.
3 Reza Green, Esq.

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☒ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:
☒ Issue Fee
☐ Publication Fee
☒ Advance Order - # of Copies 1

4b. Payment of Fee(s):
☐ A check in the amount of the fee(s) is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number 19-4516 (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) Reg No 48529 (Date) 4/28/03

05/06/2003 EAREGAY2 00000063 141447 09349748
01 FC:1501 1300.00 CH
02 FC:8001 3.00 CH

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMIT THIS FORM WITH FEE(S)

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Attorney Docket No.: 5533.200-US

PATENT

Certificate
AUG 10 2005
of Correction

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/349,748

Filed: July 8, 1999

For: Medical Device

Group Art Unit: 3763

Examiner: K. Simmons

Patent No.: 6,582,408

Issued: June 24, 2003

FACSIMILE CERTIFICATE OF TRANSMISSION
Via Facsimile No.: 571-273-8300

Certificates of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I hereby certify that the attached correspondence comprising:

1. Request for Certificate of Correction of Patent for Applicant's Mistake (in duplicate)
2. Form PTO/SB/44 (also Form PTO-1050)

is being deposited with the United States Patent and Trademark Office via facsimile no. 571-273-8300 on August 9, 2005.

Rashida Haji
(name of person mailing paper)

Rashida Haji
(signature of person mailing paper)

AUG 12 2005

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EM

Patent No. 6,582,408, issued Jun. 24, 2003
Attorney Docket No.: 5533.200-US
Via Facsimile No.: 571-273-8300
5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No:	6,582,408
Issued:	June 24, 2003
Name of Patentee:	Buch-Rasmussen et al.
Title of Invention:	Medical Device
Serial No.:	09/349,748
Examiner:	Kevin C. Simmons

Certificates of Correction Branch
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT
FOR APPLICANT'S MISTAKE [37 C.F.R. §1.323]

1. Patentees request correction of two errors in the above-referenced patent by issuance of a Certificate of Correction.

2. The first error appears in claim 1, col. 6, line 23. The text "cannot not move" (incorrect) should read "cannot move" (correct).

3. The second error appears in claim 10, col. 8, lines 5-7. The text "the cartridge assembly is positively precluded from moving axially relative to the cartridge assembly" (incorrect) should read "the cartridge assembly is positively precluded from moving axially relative to the dosage assembly" (correct).

4. Support for both of these corrections is found in the application as originally filed at page 4, lines 21-26; and in the issued patent at col. 3, lines 15-22:

> "In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle

AUG 1 2 2005

assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly."

The correct information also appears in the prosecution history in the Amendment dated August 15, 2002, at page 7, first full paragraph: "[T]he means for securing the dosing assembly to the cartridge assembly must prevent unintended axial movement of the dosage assembly relative to the cartridge assembly."

5. In each instance, the mistake is of a clerical nature, of minor character and self-evident. In view of the support in the application as filed, as well as the clear purport of the claim language, the requested corrections would not involve new matter, nor would they require reexamination of the application.

6. Attached is a copy of Form PTO/SB/44 (also Form PTO-1050), specifying a correction to each of the errors.

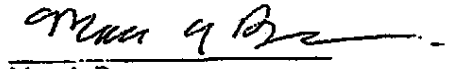
7. Please authorize and issue the Certificate of Correction to the undersigned Attorney.

Patentees attach copies of the relevant pages from the prosecution history.

8. The Commissioner is authorized to charge the fee for this Petition for Certificate of Correction per 37 C.F.R. §1.20(a), and any additional fees which may be due, to Deposit Account No.14-1447.

Dated: August 9, 2005

Respectfully submitted,



Marc A. Began
Reg. No. 48,829
Customer No. 23650
Novo Nordisk
100 College Road West
Princeton, NJ 08540
Direct Line: (609) 919-7829

Enclosures

Patent No. 6,582,408, issued Jun. 24, 2003
Attorney Docket No.: 5533.200-US
Via Facsimile No.: 571-273-8300
5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No:	6,582,408
Issued:	June 24, 2003
Name of Patentee:	Buch-Rasmussen et al.
Title of Invention:	Medical Device
Serial No.:	09/349,748
Examiner:	Kevin C. Simmons

Certificates of Correction Branch
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

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Respectfully submitted,

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Direct Line: (609) 919-7829

Enclosures

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Attorney Docket No.: 5533.200-US
Via Facsimile No.: 571-273-8300

5533.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No:	6,582,408
Issued:	June 24, 2003
Name of Patentee:	Buch-Rasmussen et al.
Title of Invention:	Medical Device
Serial No.:	09/349,748
Examiner:	Kevin C. Sirmons

Certificates of Correction Branch
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

Patent No: 6,582,408 B1
Issued: June 24, 2003
Name of Patentee: Buch-Rasmussen et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 6
Line 23: "cannot not move" should read "cannot move".

Col. 8
Line 7: "cartridge assembly" should read "dosage assembly".

MAILING ADDRESS OF SENDER:
Marc A. Began, Esq.
Novo Nordisk, Inc.
100 College Road, West
Princeton, NJ 08540

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08/09/2005 14:25 FAX 6099373095 NOVO NORDISK FINANCL RECEIVED @008/008
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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

Patent No: 6,582,408 B1
Issued: June 24, 2003
Name of Patentee: Buch-Rasmussen et al.

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MAILING ADDRESS OF SENDER
Marc A. Began, Esq.
Novo Nordisk, Inc.
100 College Road, West
Princeton, NJ 08540

PAGE 8/8 * RCVD AT 8/9/2005 3:16:16 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-6/31 * DNIS:2738300 * CSID:6099373095 * DURATION (mm-ss):01-38

AUG 1 2 2005

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,582,408 B1
DATED : June 24, 2003
INVENTOR(S) : Buch-Rasmussen et al.

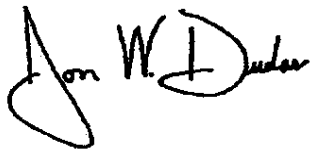
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 6,
Line 23, "cannot not move" should read -- cannot move --.

Column 8,
Line 7, "cartridge assembly" should read -- dosage assembly --.

Signed and Sealed this

Thirteenth Day of September, 2005



JON W. DUDAS
Director of the United States Patent and Trademark Office

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in ABANDONMENT of the application.

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

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Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in ABANDONMENT of the application.

ATTACHMENT TO AND MODIFICATION OF NOTICE OF ALLOWABILITY (PTO-37)

(November, 2000)

NO EXTENSIONS OF TIME ARE PERMITTED TO FILE CORRECTED OR FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION, notwithstanding any indication to the contrary in the attached Notice of Allowability (PTO-37).

If the following language appears on the attached Notice of Allowability, the portion lined through below is of no force and effect and is to be ignored:

~~A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirement noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).~~

Similar language appearing in any attachment to the Notice of Allowability, such as in an Examiner's Amendment/Comment or in a Notice of Draftperson's Patent Drawing Review, PTO-948, is also to be ignored.

The language which is crossed out is contrary to amended 37 CFR 1.85(c) and 1.136. See *Changes to Implement Patent Fees Legislation*, 65 *Fed. Reg.* 54603, 54629, 54633-34, 54670, 54674 (September 8, 2000), 1233 *Off. Gaz. Pat. Office* 77, 99, 110, 135, 139 (September 19, 2000).

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

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2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes

Timing of Corrections

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Failure to take corrective action within the set period will result in ABANDONMENT of the application.

06/01 01

PATENT APPLICATION FEE DETERMINATION RECORD

Effective November 10, 1998

Application or Docket Number: 09/349,748

CLAIMS AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA
BASIC FEE		
TOTAL CLAIMS	18 minus 20= *	—
INDEPENDENT CLAIMS	2 minus 3 = *	—
MULTIPLE DEPENDENT CLAIM PRESENT		

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐	RATE	FEE	OR	OTHER THAN SMALL ENTITY	RATE	FEE
		360.00	OR			760.00
X$ 9=			OR	X$18=		
X39=			OR	X78=		
+130=			OR	+260=		
TOTAL			OR	TOTAL		760

CLAIMS AS AMENDED - PART II

A

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 33	Minus	** 20	= 13
Independent	* 4	Minus	*** 3	= 1
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	234.00
X39=		OR	X78=	390.00
+130=		OR	+260=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

D

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 0	Minus	** 20	= —
Independent	* 0	Minus	*** 4	= —
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

No fee paid

RATE	ADDITIONAL FEE	OR	RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X39=		OR	X78=	
+130=		OR	+260=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

RATE	ADDITIONAL FEE	OR	RATE	ADDITIONAL FEE
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X39=		OR	X78=	
+130=		OR	+260=	
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* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-875 (Rev. 6/98)

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

[redacted]

SEARCHED

Class	Sub.	Date	Exmr.
604	186,187 232,188 192,195 207-218 200,201 228,233 234	11/16/00	KCS
Update	search	5/14/02	KCS
Update	search	1/23/03	KCS

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
Same	as above	1/23/03	KCS

SEARCH NOTES
(INCLUDING SEARCH STRATEGY)

	Date	Exmr.
East	11/14/00	KCS

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ISSUE SLIP STAPLE AREA (for additional cross references)

POSITION	INITIALS	ID NO.	DATE
FEE DETERMINATION	5.W	299 67094	7/29/99
O.I.P.E. CLASSIFIER	MTW	59	7-26-99
FORMALITY REVIEW		65703	8-3-99

INDEX OF CLAIMS

✓ .... Rejected		N .... Non-elected	
= .... Allowed		I .... Interference	
— (Through numeral)... Canceled		A .... Appeal	
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Claim Final	Claim Original	2/3/00	11/16/01	12/26/01	5/16/02	1/23/03					
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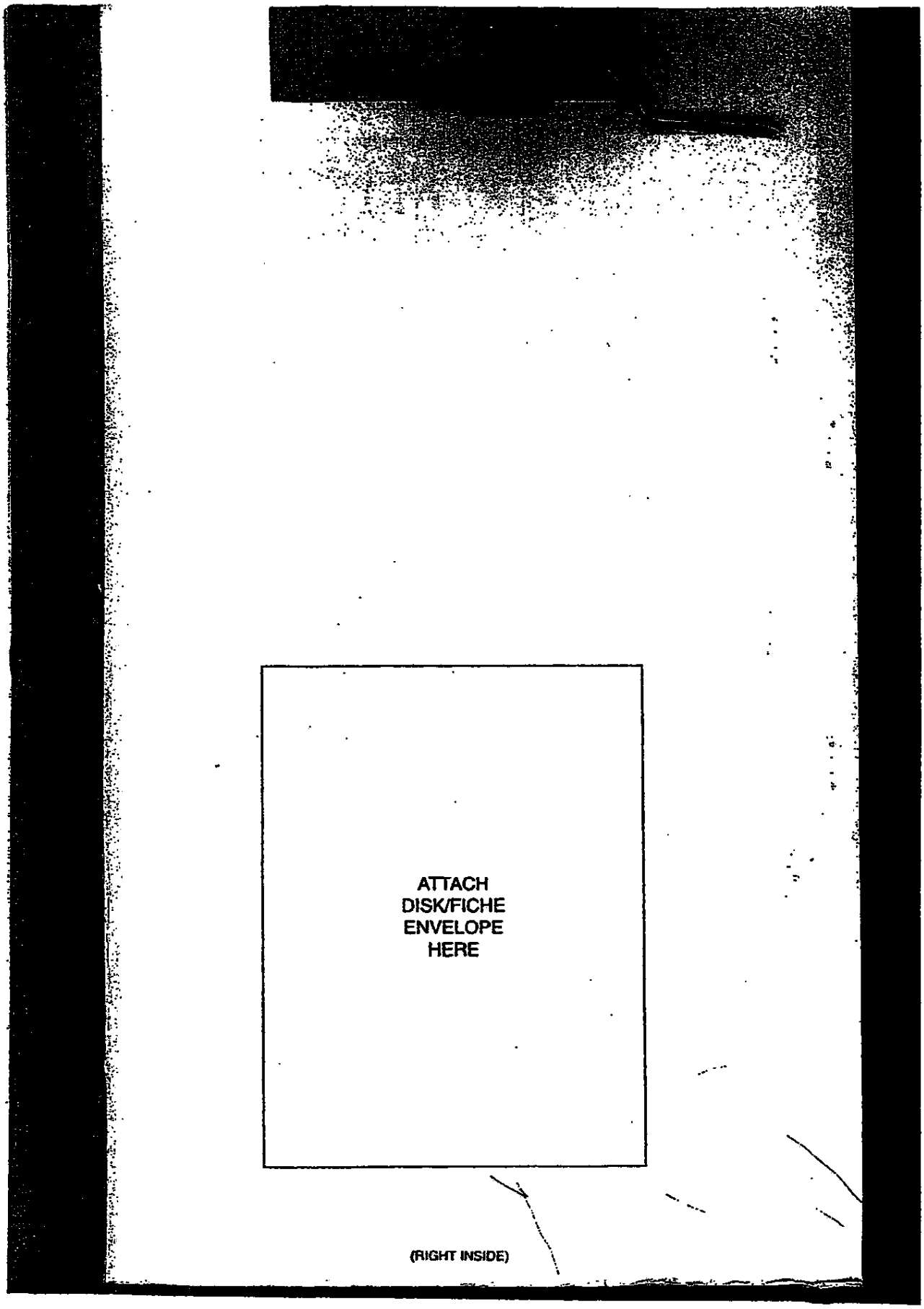
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PATENT APPLICATION
09349748

INITIALS

CONTENTS

	Date received (Incl. C. of M.) or Date Mailed		Date received (Incl. C. of M.) or Date Mailed
1. Application papers.		42.	
2. LR. Fee Signature	8-5-99	43.	
3. Decl. & Surcharge	10-7-99	44.	
4. [redacted]	1899	45.	
5. Rec'd 37 CFR	2-15-002-14	46.	
6. Prelim Amdt	11/5/99	47.	
7. IDS	02/16/00	48.	
8. Election	9-800	49.	
9. IDS (3 mos)	12-700	50.	
10. Ext of time (3 mos)	6-8-01	51.	
11. Amdt B	6-8-01	52.	
12. FINAL REJECTION (3)	8/24/01	53.	
13. Ext of Time (1)	1/9/02 cpm	54.	
14. Amdt C (N.F.)	1/9/02	55.	
15. Advisory Action	2/11/02	56.	
16. RCE/EOT (2)	2-19-02 cpm	57.	
17. Rej (3)	5-15-02	58.	
18. Amdt D	8-20-02	59.	
19. Supplemental Amdt E	1-24-03	60.	
20. Notice of Allowability	4/9/03	61.	
21. 312 Amdt 85B cpc OF ADD	05/06/03	62.	
22. CORC	8/10/05	63.	
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EXHIBIT 3

Kongeriget Danmark

PRIORITY DOCUMENT

Patent application No.: PA 1998 00910

Date of filing: 08 July 1998

Applicant: Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd

This is to certify the correctness of the following information:

The attached photocopy is a true copy of the following document:

- The specification, claims and drawings as filed with the application on the filing date indicated above.

Patent- og Varemærkestyrelsen
Erhvervsministeriet

TAASTRUP 26 November 1999

Karin Schlichting
Head Clerk

The present invention relates to a medication delivery device having a cartridge assembly and a dosing assembly coupled together for delivering selected doses of medication.

Background

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

Due to the environmental and economical reasons medication delivery pens were developed, for which pens only a part of the pen was discarded after medication exhaustion, such as the cartridge only.

An example of prior art pens is disclosed in EP 0 688 571 wherein a medication delivery pen has a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The disposable cartridge assembly includes a plunger and can releasably receive a needle cannula assembly through a threaded coupling. A driving means in the pen body assembly engages the plunger after engagement of the pen body assembly and the cartridge assembly, whereby the pen is ready for dosing the medicine within the cartridge. The cartridge

holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced.

However, a drawback of the above-mentioned pen is that the driving means of the pen body may be disengaged from the plunger of the cartridge during normal use resulting in inaccurate dosing of the medicine.

For the device disclosed in EP 0 688 571, the needle assembly will often have to be replaced independently of replacement of the cartridge. When releasing the needle assembly from the cartridge assembly the cartridge assembly may inadvertently be released or partly released from the pen body assembly. Thereby the driving means of the pen body may be disengaged from the plunger of the cartridge. In particular if the pen body assembly is only partly released from the cartridge assembly the user will most probably not be aware of the disengagement but will receive only a portion or even nothing of the medicine.

Even pens with differently pitched threaded couplings and/or threaded couplings having different diameters whereby the force exerted to fasten and/or release one coupling is greater than the force necessary for the other coupling present this problem. It is easy to imagine that a small obstruction (a sandskorn, for example) to the smoothest going coupling will necessitate a greater force to fasten/release that coupling which force tends towards the force necessary for the other coupling.

Accordingly, it is an object of the present invention to provide a medication delivery device with which the inadvertent disengagement of the driving means and plunger means from the plunger or stopper in the cartridge is avoided.

Summary of the invention

According to a first aspect of the invention a medication delivery device is provided which comprises

a cartridge assembly, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasably mounting a needle

assembly, and comprising a cartridge having a stopper adapted to receive plunger means,

a dosing assembly comprising plunger means,

and optionally a needle assembly,

wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

By the term "use of the device" is meant the normal use, including measuring and delivering the medication, removing a cap from the cartridge assembly and/or needle as well as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from the dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

Furthermore, it is a preferred aspect of the invention to provide a medication delivery device, which device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly.

In one embodiment of the invention the dosing assembly is coupled to the cartridge assembly at the end of the cartridge assembly opposite the means for mounting the needle assembly, and the plunger means is a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.

Accordingly, it is an aspect of the present invention to provide a medication delivery device, wherein the means for coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly. In this way it is assured that the rod element does not disengage the stopper in the cartridge when the user attaches the needle assembly or removes it after use. Thereby the user can be confident of the accuracy of the dosage selected

The means for coupling the dosing assembly and the cartridge assembly together may be any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

According to the invention preferred combinations of couplings between the dosing assembly and the cartridge assembly and between the needle assembly and the cartridge assembly, respectively, are a threaded coupling combined with a snap

coupling, a bajonet lock or a luer lock combined with a snap lock, or a snap lock combined with a snap lock, or any other combination for which the couplings are independently working.

Another aspect of the present invention is a cartridge assembly for use in the medication delivery device according to the invention The cartridge assembly comprises a cartridge for the medication to be delivered. The cartridge assembly has one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasable mounting a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly. Furthermore, the cartridge comprises a stopper.

The cartridge assembly may further comprise a housing for protecting at least a part of the cartridge assembly.

In a preferred embodiment at least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge, and in a more preferred embodiment all the coupling means are unitarily moulded with the cartridge. In the latter case the cartridge assembly may be comprised of just one part, i.e. the cartridge including the coupling means.

Drawings

Fig. 1 is an exploded perspective view of the medication delivery device.

Fig 2 is a cross-sectional view showing part of the medication delivery device, 2a immediately after assembling before the first injection, and 2b after some time of use

Fig 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

Detailed description of the invention

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in Fig. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 16 and a cap 14.

The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3. In Fig. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6.

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one or both of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

In a preferred embodiment at least one of the couplings 2, 3 is moulded unitarily with the cartridge 5, minimising the total number of parts of the device and thereby the production costs

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall.

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

In Fig. 1 and Fig. 2 the couplings 2, 3 are opposing each other. However, coupling 2 being separate from coupling 3 may be arranged in any angle with respect to coupling 3.

A suitable choice of material allows the cartridge to be at least partly transparent, whereby the user can see whether liquid is left in the cartridge.

Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will effect the stopper 4 to be moved towards the needle at the sealed end 22 of the cartridge 5, thereby delivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as

starting point. Dose setting and injections can be carried out until all of the medication has been used.

Claims:

1. A medication delivery device comprising

a cartridge assembly, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and comprising a cartridge having a stopper adapted to receive plunger means,

a dosing assembly comprising plunger means,

and optionally a needle assembly,

wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.

2. A medication delivery device according to claim 1, wherein the dosing assembly is releasably coupled to the cartridge assembly.

3. A medication delivery device according to any of the preceding claims, wherein the device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly.

4. A medication delivery device according to any of the preceding claims, wherein the plunger means comprises a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.

5. A medication delivery device according to any of the preceding claims, wherein the means for releasably coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly.

6. A medication delivery device according to any of the preceding claims, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement

7. A medication delivery device according to claim 6, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.

8. A medication delivery device according to any of the preceding claims, wherein the dosing assembly comprises scale means.

9. A medication delivery device according to any of the preceding claims, wherein the dosing assembly comprises dose setting means for defining specified selected doses of medication to be delivered

10. A medication delivery device according to any of the preceding claims, wherein the cartridge assembly comprises a housing.

11. A medication delivery device according to any of the preceding claims, wherein the cartridge is unitarily moulded with at least one coupling means.

12. A medication delivery device according to any of the preceding claims, further comprising a cap for protecting the needle assembly and/or the cartridge assembly.

13. A cartridge assembly for use in the medication delivery device as claimed in any of claims 1-12, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly, further comprising a cartridge said cartridge comprising a slidable stopper

14. A cartridge assembly according to claim 13, further comprising a housing.

15. A cartridge assembly according to claim 13 or 14, wherein the cartridge is unitarily moulded with at least one coupling means.

16. A cartridge assembly according to any of claims 13-15, wherein the coupling means adapted to engage the dosing unit is such that coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly.

17. A cartridge assembly according to any of claims 13-16, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement

18. A cartridge assembly according to claim 17, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.

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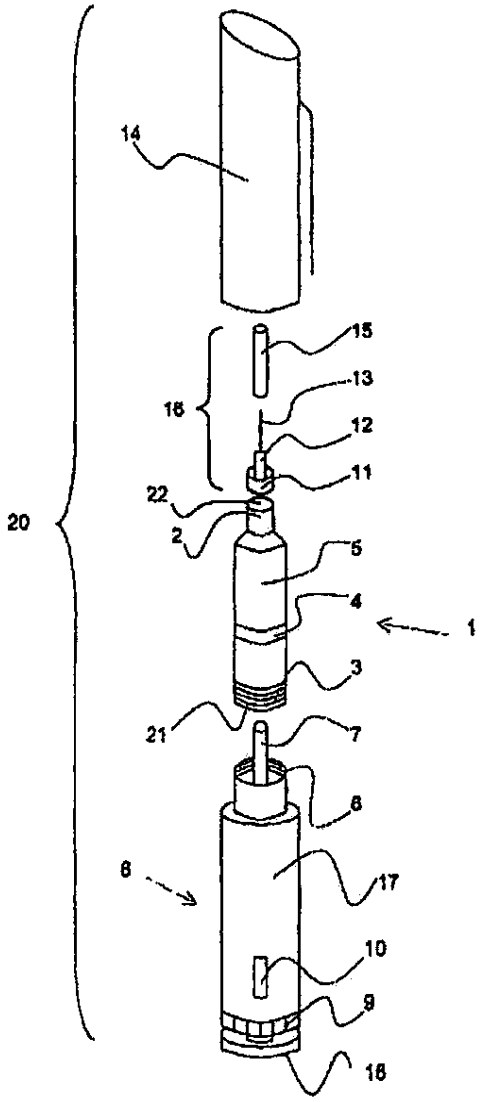

Fig. 1

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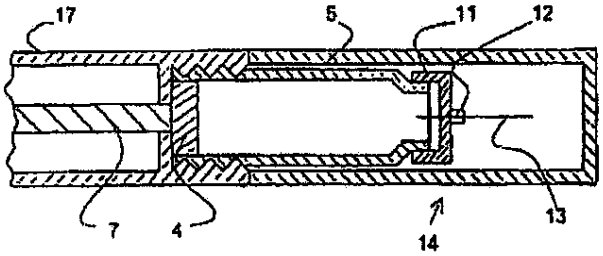

Fig. 2 a

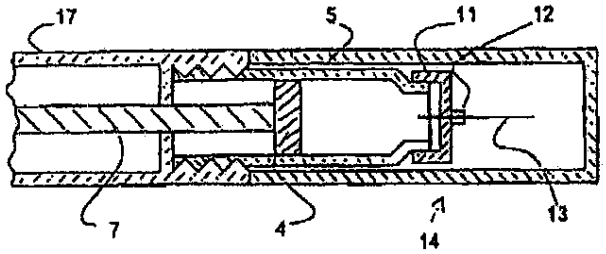

Fig. 2 b

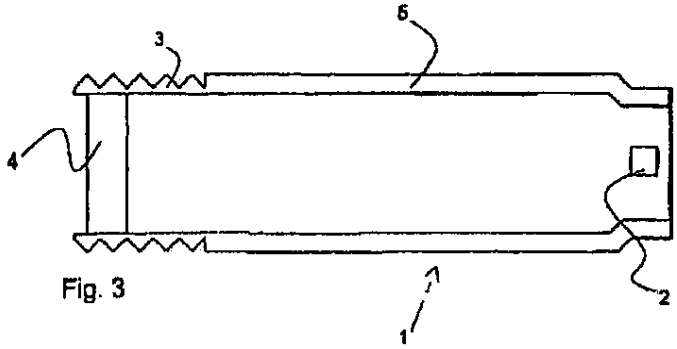

Fig. 3

EXHIBIT 4

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UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

June 28, 2006

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APPLICATION NUMBER: *60/098,707*

FILING DATE: *September 01, 1998*

By Authority of the

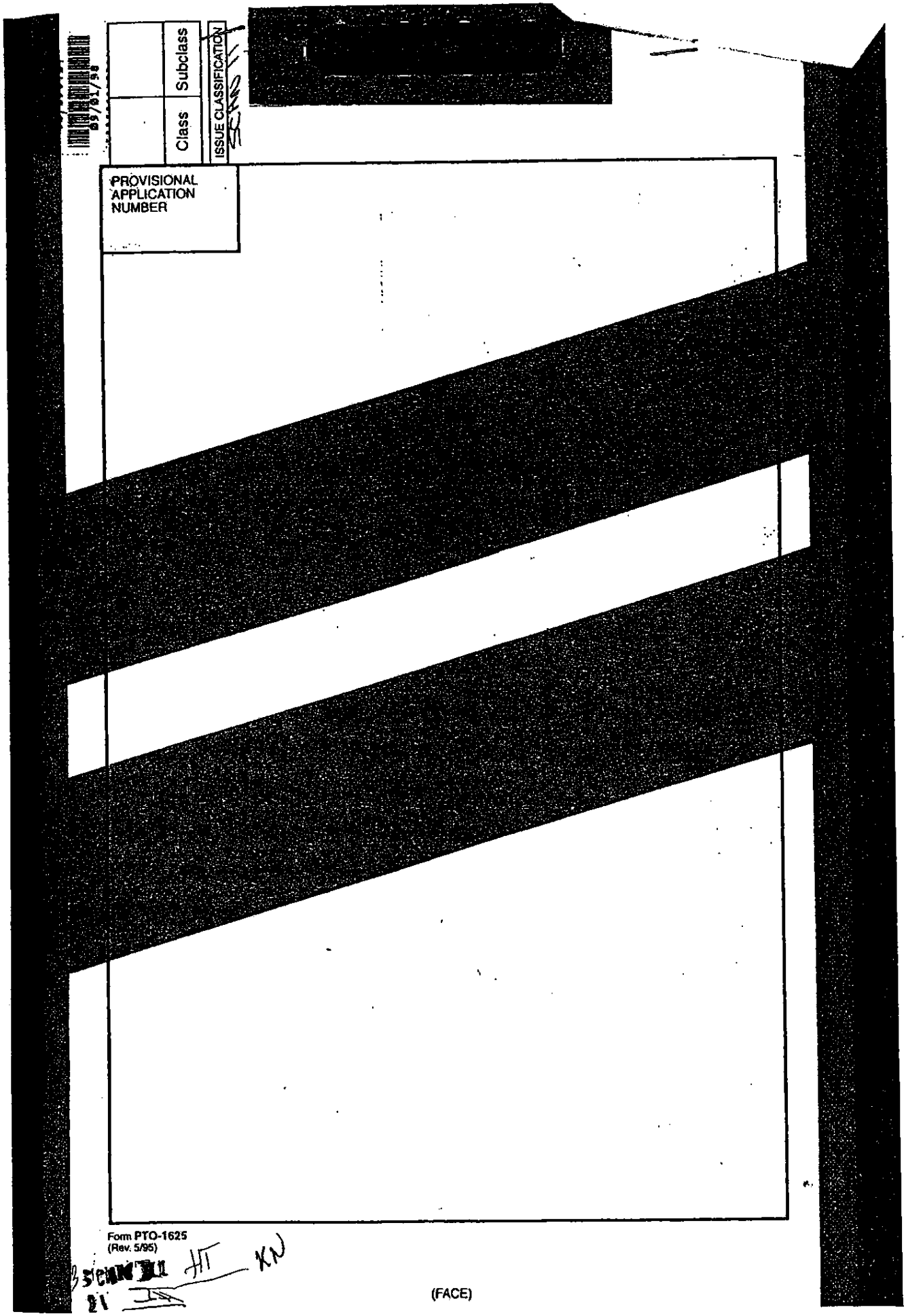
Under Secretary of Commerce for Intellectual Property

and Director of the United States Patent and Trademark Office

J. Montgomery

J. MONTGOMERY

Certifying Officer


Subclass
Class
ISSUE CLASSIFICATION
PROVISIONAL APPLICATION NUMBER
Form PTO-1625
(Rev. 5/95)
(FACE)

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
60/098,707 PROVISIONAL	09/01/98		0000	5533.003-US

APPLICANT

THOMAS BUCH-RASSMUSSEN, GENTOFTE, DENMARK; BENNY MUNK, VANLOSE, DENMARK; JENS-ULRIK POULSEN, VIRUM, DENMARK; HENRIK LJUNGREEN, BALLERUP, DENMARK; PETER MOLLER JENSEN, HORSHOLM, DENMARK; JENS MOLLER JENSEN, KOBENHAVN K, DENMARK.

CONTINUING DOMESTIC DATA********
VERIFIED

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371 (NAT'L STAGE) DATA********
VERIFIED

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FOREIGN APPLICATIONS********
VERIFIED

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Foreign Priority claimed 35 USC 119 (a-d) conditions met	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐yes ☐no ☐yes ☐no ☐Met after Allowance Verified and Acknowledged _____ Examiner's Initials _____ Initials	DKX	2		

ADDRESS

STEVE T ZELSON
NOVO NORDISK OF NORTH AMERICA INC
405 LEXINGTON AVENUE
SUITE 6400
NEW YORK NY 10174-6401

TITLE

MEDICAL DEVICE

FILING FEE RECEIVED	FEES: Authority has been given in Paper	
$150	No. _____ to charge/credit DEPOSIT ACCOUNT NO. _____ for the following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

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PTO-1556
(5/87)

A/P60V

Attorney Docket No.: 5533.003-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

EXPRESS MAIL CERTIFICATE

Assistant Commissioner for Patents
Washington, DC 20231

Re: U.S. Provisional Application for
"Medical Device"
Applicants: Buch-Rasmussen.et al.

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Attorney Docket No.: 5533.003-US PATENT

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Sir:

This is a request for filing a provisional application under 37 C.F.R. §1.53(c), of the inventors:

Büch-Rasmussen, Thomas, a citizen of Denmark, residing at Dalvej 28, DK-2820 Gentofte, Denmark;

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Jensen, Jens Møller, a citizen of Denmark, residing at Nyhavn 37, DK-1051 København K, Denmark

for application entitled: **Medical Device.**

The provisional application contains:

12 pages of specification

2 sheets of drawings

Address all future communications to Steve T. Zelson, Esq., Novo Nordisk of North America, Inc., 405 Lexington Avenue, Suite 6400, New York, NY 10174-6401.

Please charge the required fee, estimated to be $150, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: September 1, 1998

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The present invention relates to a medication delivery device having a cartridge assembly and a dosing assembly coupled together for delivering selected doses of medication.

Background

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

Due to the environmental and economical reasons medication delivery pens were developed, for which pens only a part of the pen was discarded after medication exhaustion, such as the cartridge only.

An example of prior art pens is disclosed in EP 0 688 571 wherein a medication delivery pen has a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The disposable cartridge assembly includes a plunger and can releasably receive a needle cannula assembly through a threaded coupling. A driving means in the pen body assembly engages the plunger after engagement of the pen body assembly and the cartridge assembly, whereby the pen is ready for dosing the medicine within the cartridge. The cartridge

holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced.

However, a drawback of the above-mentioned pen is that the driving means of the pen body may be disengaged from the plunger of the cartridge during normal use resulting in inaccurate dosing of the medicine.

For the device disclosed in EP 0 688 571, the needle assembly will often have to be replaced independently of replacement of the cartridge. When releasing the needle assembly from the cartridge assembly the cartridge assembly may inadvertently be released or partly released from the pen body assembly. Thereby the driving means of the pen body may be disengaged from the plunger of the cartridge. In particular if the pen body assembly is only partly released from the cartridge assembly the user will most probably not be aware of the disengagement but will receive only a portion or even nothing of the medicine.

Even pens with differently pitched threaded couplings and/or threaded couplings having different diameters whereby the force exerted to fasten and/or release one coupling is greater than the force necessary for the other coupling present this problem. It is easy to imagine that a small obstruction (a sandskorn, for example) to the smoothest going coupling will necessitate a greater force to fasten/release that coupling which force tends towards the force necessary for the other coupling.

Accordingly, it is an object of the present invention to provide a medication delivery device with which the inadvertent disengagement of the driving means and plunger means from the plunger or stopper in the cartridge is avoided.

Summary of the invention

According to a first aspect of the invention a medication delivery device is provided which comprises

a cartridge assembly, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasably mounting a needle

assembly, and comprising a cartridge having a stopper adapted to receive plunger means,

a dosing assembly comprising plunger means,

and optionally a needle assembly,

wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

By the term "use of the device" is meant the normal use, including measuring and delivering the medication, removing a cap from the cartridge assembly and/or needle as well as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from the dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

Furthermore, it is a preferred aspect of the invention to provide a medication delivery device, which device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly.

In one embodiment of the invention the dosing assembly is coupled to the cartridge assembly at the end of the cartridge assembly opposite the means for mounting the needle assembly, and the plunger means is a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.

Accordingly, it is an aspect of the present invention to provide a medication delivery device, wherein the means for coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly. In this way it is assured that the rod element does not disengage the stopper in the cartridge when the user attaches the needle assembly or removes it after use. Thereby the user can be confident of the accuracy of the dosage selected.

The means for coupling the dosing assembly and the cartridge assembly together may be any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

According to the invention preferred combinations of couplings between the dosing assembly and the cartridge assembly and between the needle assembly and the cartridge assembly, respectively, are a threaded coupling combined with a snap

coupling, a bajonet lock or a luer lock combined with a snap lock, or a snap lock combined with a snap lock, or any other combination for which the couplings are independently working.

Another aspect of the present invention is a cartridge assembly for use in the medication delivery device according to the invention. The cartridge assembly comprises a cartridge for the medication to be delivered. The cartridge assembly has one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasable mounting a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly. Furthermore, the cartridge comprises a stopper.

The cartridge assembly may further comprise a housing for protecting at least a part of the cartridge assembly.

In a preferred embodiment at least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge, and in a more preferred embodiment all the coupling means are unitarily moulded with the cartridge. In the latter case the cartridge assembly may be comprised of just one part, i.e. the cartridge including the coupling means.

Drawings

Fig. 1 is an exploded perspective view of the medication delivery device.

Fig. 2 is a cross-sectional view showing part of the medication delivery device, 2a immediately after assembling before the first injection, and 2b after some time of use.

Fig. 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

Detailed description of the invention

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in Fig. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 16 and a cap 14.

The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3. In Fig. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above.

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6.

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one or both of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

In a preferred embodiment at least one of the couplings 2, 3 is moulded unitarily with the cartridge 5, minimising the total number of parts of the device and thereby the production costs.

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall.

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

In Fig. 1 and Fig. 2 the couplings 2, 3 are opposing each other. However, coupling 2 being separate from coupling 3 may be arranged in any angle with respect to coupling 3.

A suitable choice of material allows the cartridge to be at least partly transparent, whereby the user can see whether liquid is left in the cartridge.

Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will effect the stopper 4 to be moved towards the needle at the sealed end 22 of the cartridge 5, thereby delivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as

starting point. Dose setting and injections can be carried out until all of the medica tion has been used.

Claims:

1. A medication delivery device comprising

a cartridge assembly, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and comprising a cartridge having a stopper adapted to receive plunger means,

a dosing assembly comprising plunger means,

and optionally a needle assembly,

wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.

2. A medication delivery device according to claim 1, wherein the dosing assembly is releasably coupled to the cartridge assembly.

3. A medication delivery device according to any of the preceding claims, wherein the device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly.

4. A medication delivery device according to any of the preceding claims, wherein the plunger means comprises a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.

5. A medication delivery device according to any of the preceding claims, wherein the means for releasably coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly.

6. A medication delivery device according to any of the preceding claims, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement.

7. A medication delivery device according to claim 6, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.

8. A medication delivery device according to any of the preceding claims, wherein the dosing assembly comprises scale means.

9. A medication delivery device according to any of the preceding claims, wherein the dosing assembly comprises dose setting means for defining specified selected doses of medication to be delivered.

10. A medication delivery device according to any of the preceding claims, wherein the cartridge assembly comprises a housing.

11. A medication delivery device according to any of the preceding claims, wherein the cartridge is unitarily moulded with at least one coupling means.

12. A medication delivery device according to any of the preceding claims, further comprising a cap for protecting the needle assembly and/or the cartridge assembly.

13. A cartridge assembly for use in the medication delivery device as claimed in any of claims 1-12, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly, further comprising a cartridge said cartridge comprising a slidable stopper.

14. A cartridge assembly according to claim 13, further comprising a housing.

15. A cartridge assembly according to claim 13 or 14, wherein the cartridge is unitarily moulded with at least one coupling means.

16. A cartridge assembly according to any of claims 13-15, wherein the coupling means adapted to engage the dosing unit is such that coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly.

17. A cartridge assembly according to any of claims 13-16, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement.

18. A cartridge assembly according to claim 17, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.

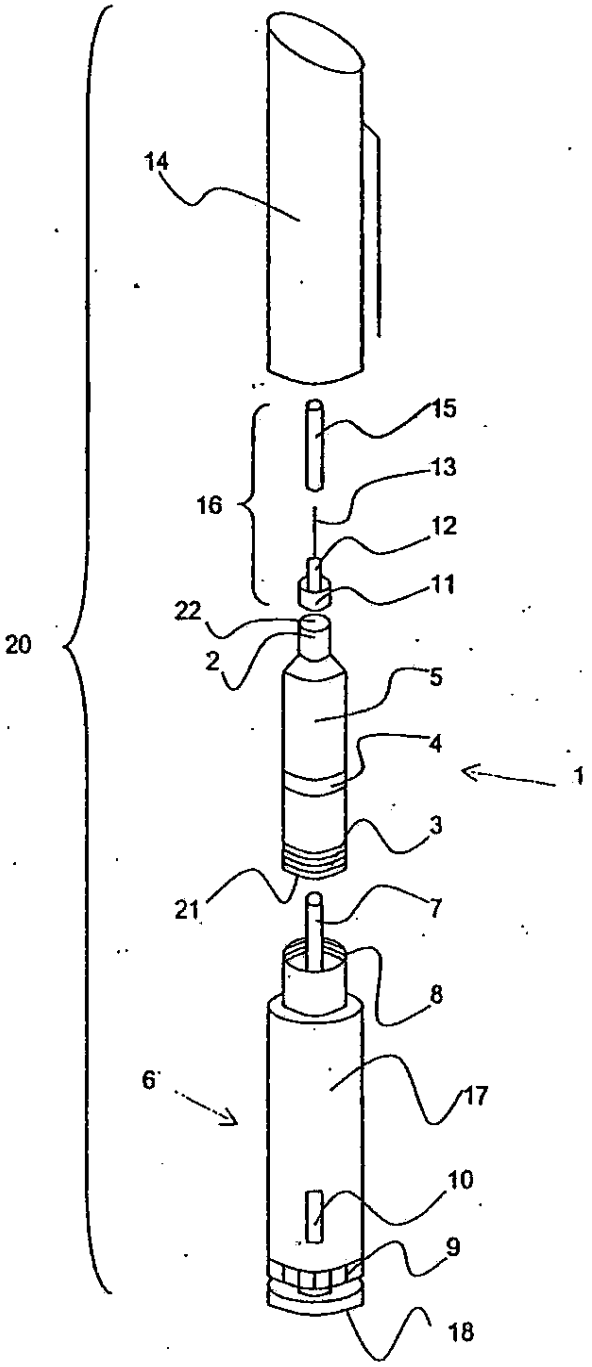

Fig. 1

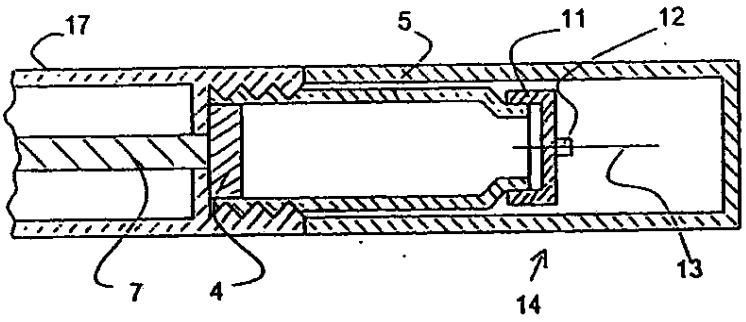

Fig. 2 a

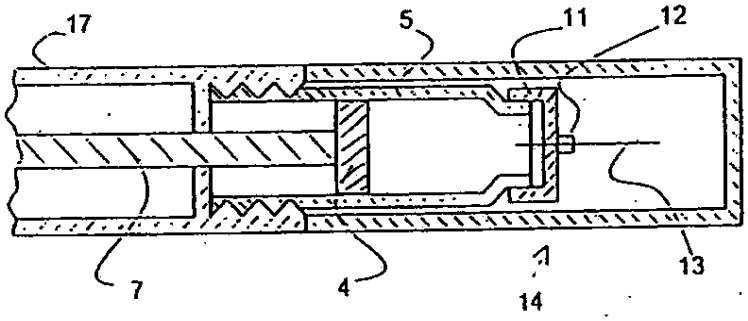

Fig. 2 b

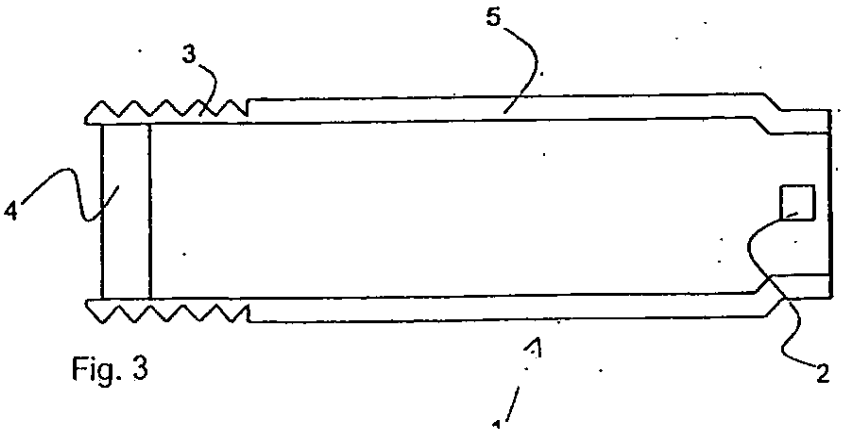

Fig. 3

PTO/SB/68 (11-04)
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(12) **United States Patent**
Buch-Rasmussen et al.

(10) **Patent No.: US 6,582,408 B1**
(45) **Date of Patent: Jun. 24, 2003**

(54) **MEDICAL DEVICE**

(76) Inventors: **Thomas Buch-Rasmussen**, Dalvej 28, DK-2820 Gentofte (DK); **Benny Munk**, Bjørverskov Allé 52, DK-2650 Hvidovre (DK); **Jens Ulrik Poulsen**, Virumgade 54 C, DK-2830 Virum (DK); **Henrik Ljungreen**, Jonstrupvej 244A, DK-2750 Ballerup (DK); **Peter Møller Jensen**, Svenstrupvej 6, D-2970 Hørsholm (DK); **Jens Møller Jensen**, Nyhavn 37, DK-1051 Copenhagen K (DK)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/349,748**

(22) Filed: **Jul. 8, 1999**

Related U.S. Application Data

(60) Provisional application No. 60/098,707, filed on Sep. 1, 1998.

(30) **Foreign Application Priority Data**

Jul. 8, 1998 (DK) ..... PA 1998 00910
Nov. 17, 1998 (DK) ..... PA 1998 01501

(51) Int. Cl.[7] A61M 5/00
(52) U.S. Cl. 604/232; 604/187
(58) Field of Search 604/186, 187, 604/232, 188, 192, 195, 207-218, 200, 201, 228, 233, 234

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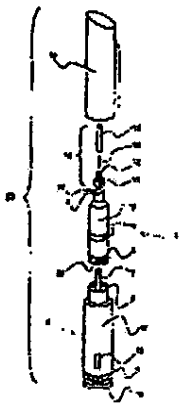
Primary Examiner—Brian L. Casler
Assistant Examiner—Kevin C. Simmons
(74) *Attorney, Agent, or Firm*—Marc A. Began, Esq.; Richard W. Bork, Esq.; Reza Green, Esq.

(57) **ABSTRACT**

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger. Furthermore, the cartridge assembly has one end sealed with a pierceable sealing, said end comprising coupling device for engaging a needle assembly, and another end comprising coupling device for engaging the dosing assembly. The dosing assembly comprises a plunger and has coupling device for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The device further comprises mechanism for securing that the plunger abuts on the stopper during use of the device, in particular when the dosing assembly is releasable coupled to the cartridge assembly. The securing mechanism is preferably a mechanism for preventing the cartridge assembly from being inadvertently released from the dosing assembly. The cartridge is preferably molded from a plastic material, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The medication delivery device is especially suitable for delivering insulin, growth hormone or the like medicines.

11 Claims, 2 Drawing Sheets



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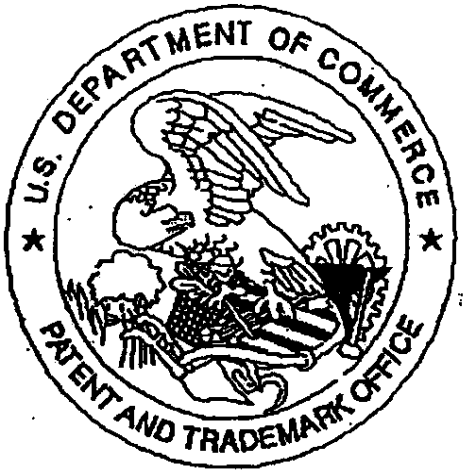

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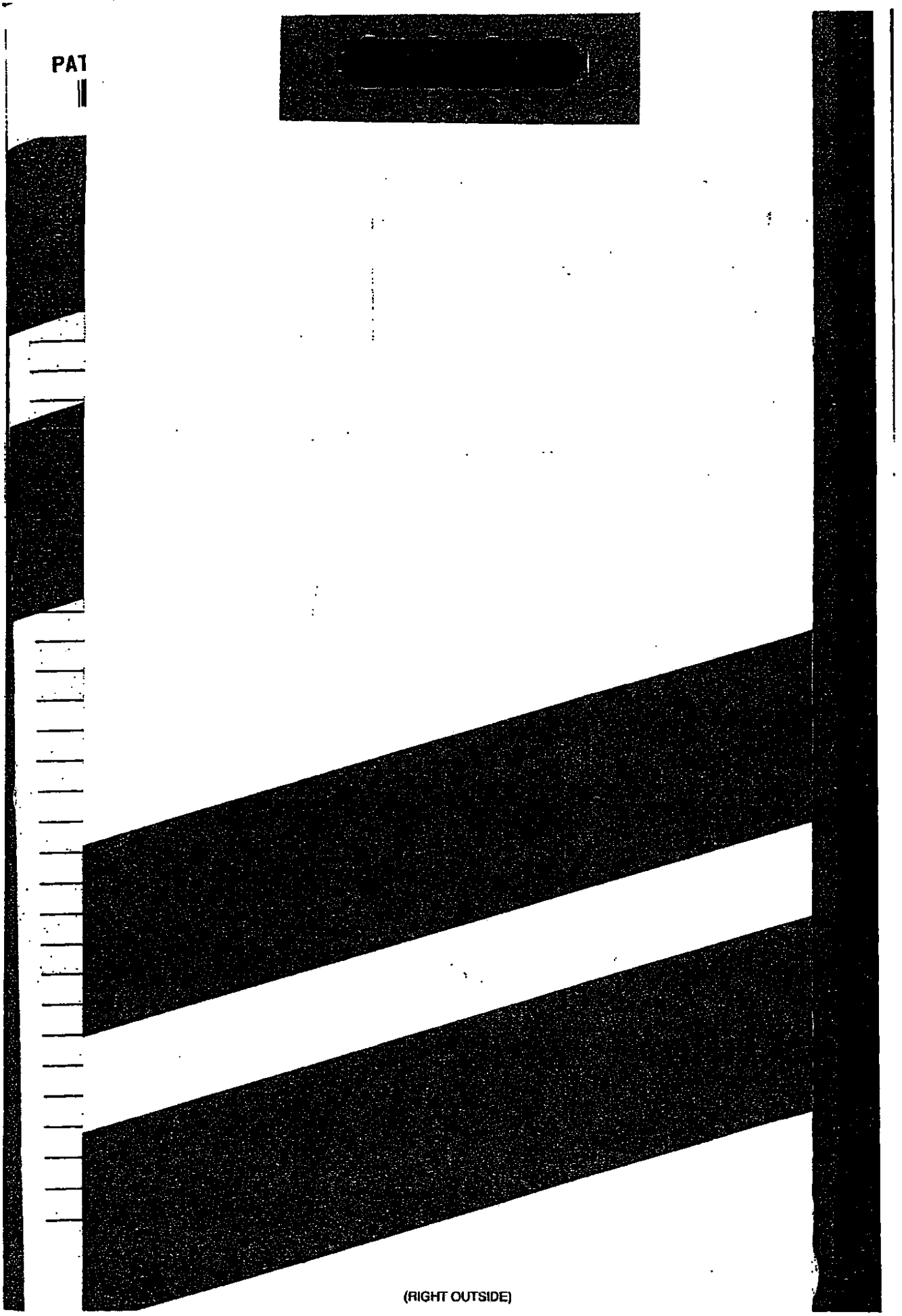
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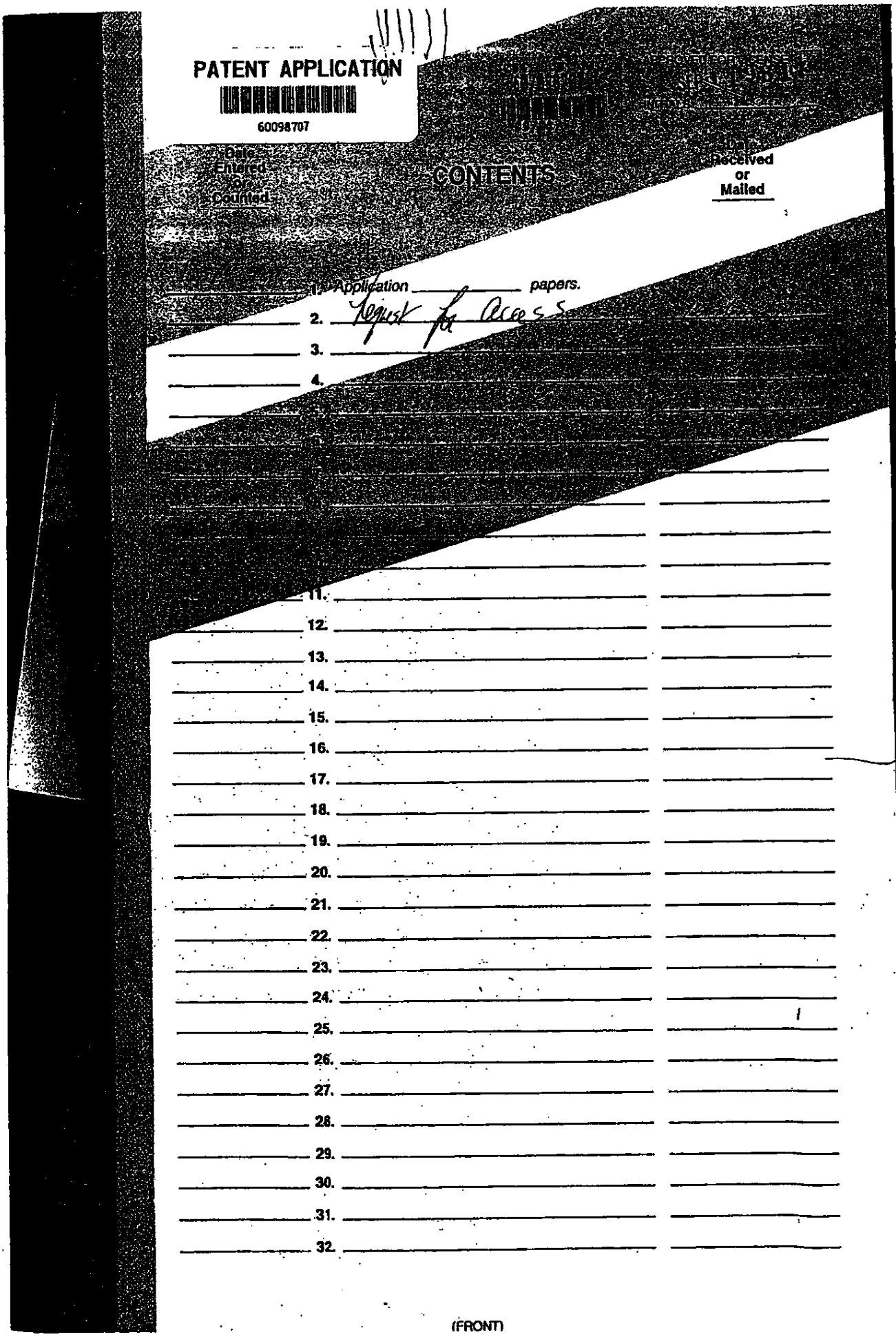

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EXHIBIT 5

Kongeriget Danmark

PRIORITY DOCUMENT

Patent application No : PA 1998 01501

Date of filing: 17 November 1998

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Erhvervsministeriet

TAASTRUP 26 November 1999

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The present invention relates to a medication delivery device having a cartridge assembly and a dosing assembly coupled together for delivering selected doses of medication.

Background

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

Due to the environmental and economical reasons medication delivery pens were developed, for which pens only a part of the pen was discarded after medication exhaustion, such as the cartridge only

An example of prior art pens is disclosed in EP 0 688 571 wherein a medication delivery pen has a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The disposable cartridge assembly includes a plunger and can releasably receive a needle cannula assembly through a threaded coupling. A driving means in the pen body assembly engages the plunger after engagement of the pen body assembly and the cartridge assembly, whereby the pen is ready for dosing the medicine within the cartridge. The cartridge

holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced

However, a drawback of the above-mentioned pen is that the driving means of the pen body may be disengaged from the plunger of the cartridge during normal use resulting in inaccurate dosing of the medicine.

For the device disclosed in EP 0 666 571, the needle assembly will often have to be replaced independently of replacement of the cartridge. When releasing the needle assembly from the cartridge assembly the cartridge assembly may inadvertently be released or partly released from the pen body assembly. Thereby the driving means of the pen body may be disengaged from the plunger of the cartridge. In particular if the pen body assembly is only partly released from the cartridge assembly the user will most probably not be aware of the disengagement but will receive only a portion or even nothing of the medicine

Even pens with differently pitched threaded couplings and/or threaded couplings having different diameters whereby the force exerted to fasten and/or release one coupling is greater than the force necessary for the other coupling present this problem. It is easy to imagine that a small obstruction (a sandskorn, for example) to the smoothest going coupling will necessitate a greater force to fasten/release that coupling which force tends towards the force necessary for the other coupling.

Accordingly, it is an object of the present invention to provide a medication delivery device with which the inadvertent disengagement of the driving means and plunger means from the plunger or stopper in the cartridge is avoided.

Summary of the invention

According to a first aspect of the invention a medication delivery device is provided which comprises

a cartridge assembly, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasably mounting a needle

assembly, and comprising a cartridge having a stopper adapted to receive plunger means,

a dosing assembly comprising plunger means,

and optionally a needle assembly,

wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

By the term "use of the device" is meant the normal use, including measuring and delivering the medication, removing a cap from the cartridge assembly and/or needle as well as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from the dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

Furthermore, it is a preferred aspect of the invention to provide a medication delivery device, which device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly

In one embodiment of the invention the dosing assembly is coupled to the cartridge assembly at the end of the cartridge assembly opposite the means for mounting the needle assembly, and the plunger means is a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.

Accordingly, it is an aspect of the present invention to provide a medication delivery device, wherein the means for coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly. In this way it is assured that the rod element does not disengage the stopper in the cartridge when the user attaches the needle assembly or removes it after use. Thereby the user can be confident of the accuracy of the dosage selected.

The means for coupling the dosing assembly and the cartridge assembly together may be any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

According to the invention preferred combinations of couplings between the dosing assembly and the cartridge assembly and between the needle assembly and the cartridge assembly, respectively, are a threaded coupling combined with a snap

coupling, a bajonet lock or a luer lock combined with a snap lock, or a snap lock combined with a snap lock, or any other combination for which the couplings are independently working.

Another aspect of the present invention is a cartridge assembly for use in the medication delivery device according to the invention. The cartridge assembly comprises a cartridge for the medication to be delivered. The cartridge assembly has one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasable mounting a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly. Furthermore, the cartridge comprises a stopper.

The cartridge assembly may further comprise a housing for protecting at least a part of the cartridge assembly.

In a preferred embodiment at least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge, and in a more preferred embodiment all the coupling means are unitarily moulded with the cartridge. In the latter case the cartridge assembly may be comprised of just one part, i.e. the cartridge including the coupling means.

In another embodiment the invention relates to a medication delivery device for transferring medication from the cartridge into a syringe with a needle. In this embodiment the coupling means for engaging the needle assembly may be replaced by coupling means for engaging the syringe, or coupling means for both may be provided. The coupling means may be a syringe holder, for example a cylinder coupled to the cartridge comprising a central bore for receiving the syringe. The syringe is coupled to the cartridge having the needle piercing the sealing. By activation of the dosing means the metered amount of medication is driven into the syringe. The syringe is then ready for injection after being removed from the cartridge.

Drawings

Fig. 1 is an exploded perspective view of the medication delivery device.

Fig. 2 is a cross-sectional view showing part of the medication delivery device, 2a immediately after assembling before the first injection, and 2b after some time of use

Fig. 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

Detailed description of the invention

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in Fig. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 16 and a cap 14.

The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3. In Fig. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one or both of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

In a preferred embodiment at least one of the couplings 2, 3 is moulded unitarily with the cartridge 5, minimising the total number of parts of the device and thereby the production costs.

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

In Fig. 1 and Fig. 2 the couplings 2, 3 are opposing each other. However, coupling 2 being separate from coupling 3 may be arranged in any angle with respect to coupling 3

A suitable choice of material allows the cartridge to be at least partly transparent, whereby the user can see whether liquid is left in the cartridge.

Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

The various parts of the medication delivery device are advantageously made of plastics, e g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will effect the stopper 4 to be moved towards the needle at the sealed end 22 of the cartridge 6, thereby delivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.

Claims:

1. A medication delivery device comprising

a cartridge assembly, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and comprising a cartridge having a stopper adapted to receive plunger means,

a dosing assembly comprising plunger means,

and optionally a needle assembly,

wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.

2. A medication delivery device according to claim 1, wherein the dosing assembly is releasably coupled to the cartridge assembly.

3. A medication delivery device according to any of the preceding claims, wherein the device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly.

4. A medication delivery device according to any of the preceding claims, wherein the plunger means comprises a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.

5 A medication delivery device according to any of the preceding claims, wherein the means for releasably coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly

6. A medication delivery device according to any of the preceding claims, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement

7. A medication delivery device according to claim 6, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.

8. A medication delivery device according to any of the preceding claims, wherein the dosing assembly comprises scale means.

9 A medication delivery device according to any of the preceding claims, wherein the dosing assembly comprises dose setting means for defining specified selected doses of medication to be delivered.

10. A medication delivery device according to any of the preceding claims, wherein the cartridge assembly comprises a housing

11. A medication delivery device according to any of the preceding claims, wherein the cartridge is unitarily moulded with at least one coupling means.

12. A medication delivery device according to any of the preceding claims, further comprising a cap for protecting the needle assembly and/or the cartridge assembly.

13. A cartridge assembly for use in the medication delivery device as claimed in any of claims 1-12, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly, further comprising a cartridge said cartridge comprising a slidable stopper.

14. A cartridge assembly according to claim 13, further comprising a housing.

15. A cartridge assembly according to claim 13 or 14, wherein the cartridge is unitarily moulded with at least one coupling means

16. A cartridge assembly according to any of claims 13-15, wherein the coupling means adapted to engage the dosing unit is such that coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly.

17 A cartridge assembly according to any of claims 13-16, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement.

18 A cartridge assembly according to claim 17, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.

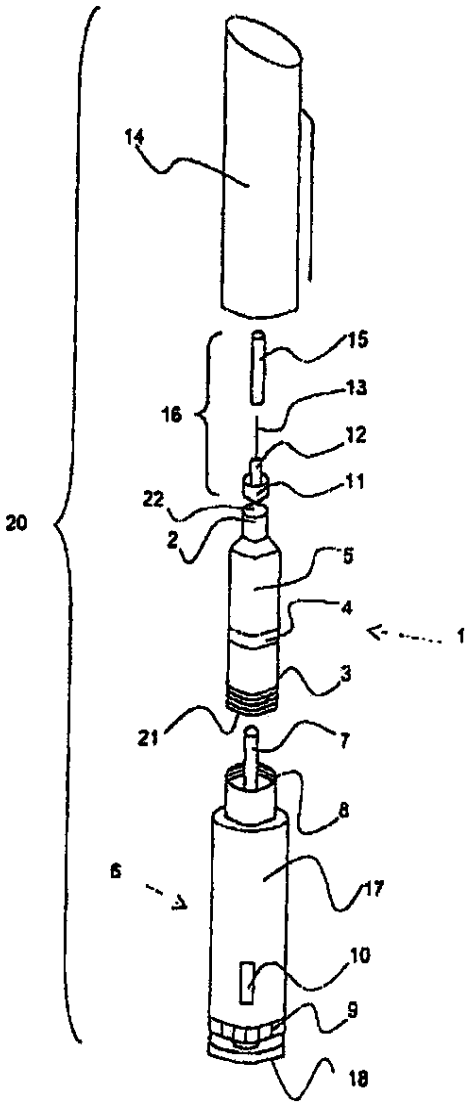

Fig. 1

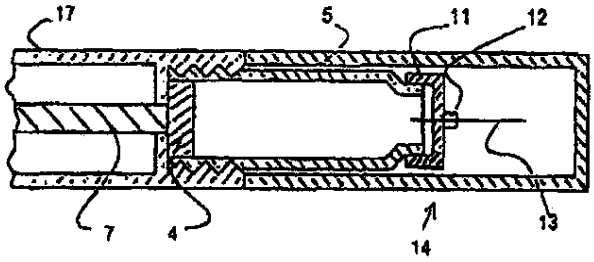

Fig. 2 a

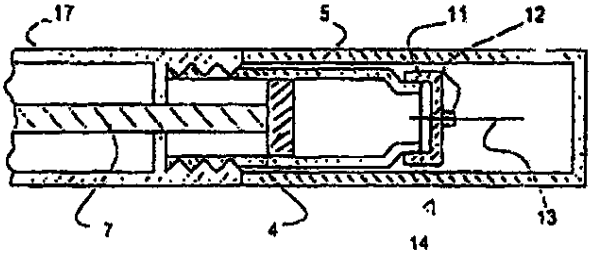

Fig. 2 b

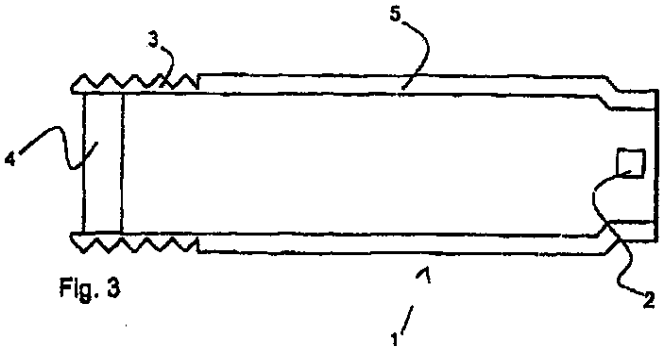

Fig. 3